May 7, 2013

The Honorable Fred Upton
Chairman, Committee on Energy and Commerce
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Joseph R. Pitts
Chairman, Subcommittee on Health
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Henry Waxman
Ranking Member, Committee on Energy and Commerce
Health Committee on Energy and Commerce
2322A Rayburn House Office Building
Washington, DC 20515

The Honorable Frank Pallone
Ranking Member, Subcommittee on
Committee on Energy and Commerce
2322A Rayburn House Office Building
Washington, DC 20515

Re: Energy and Commerce Health Subcommittee markup to amend the Federal Food, Drug, and Cosmetic Act with respect to the pharmaceutical distribution supply chain

Dear Chairman Upton, Chairman Pitts, Ranking Member Waxman, and Ranking Member Pallone:

Thank you for the opportunity to provide comments on the pharmaceutical supply chain legislation being marked up on May 7 and May 8.

We are writing on behalf of consumers, patients, scientists, and public health advocates to express our strong support for a drug distribution system that will protect patients and the public's health from unsafe medicines. The ongoing threat to the U.S. drug supply must be addressed through a strong national serialization and traceability system to track and authenticate medicines at the unit level. Without such a system to track and authenticate drugs at the unit level as they move from manufacturer to wholesaler to pharmacy to patient, the public's health continues to be placed at risk from unsafe or counterfeit medicines.

The Subcommittee on Health's proposed legislation, as currently written, lacks necessary and clearly defined elements to guarantee a unit-level serialization and traceability system in a timely manner. This is a serious patient safety concern, and must be rectified. The proposed legislation would also eliminate all existing state drug pedigree laws – major tools for law enforcement – and would leave the U.S. pharmaceutical supply unprotected for a full two years before putting a limited system in place.

We do not support a federal law that preempts existing strong state laws. The federal law should be a floor, not a ceiling. Any federal law must create a system that includes the following elements within a timely manner:

Participation of all members of the supply chain
We need full participation of all supply chain stakeholders in a unit-level serialization and traceability system to protect the integrity of the supply chain. Pharmacies are the last step in drug distribution before medicine reaches a patient and are essential for ensuring pharmaceutical integrity.

Traceability of drugs at the smallest saleable unit level
The legislation needs to create a clear, assured path to a unit-level traceability system. The proposal takes away strong existing state drug pedigree requirements, and does not replace them with assurances that unit-level traceability will be achieved. The legislation's requirement for numerous studies and meetings and lack of requirement for a final rule will create years of regulatory uncertainty and will not protect the public's health.

Routine checking and verification of drug serial numbers
The legislation calls for limited verification under an interim system, and does not create a meaningful framework to achieve enhanced verification. A robust system should include proactive verification of drug units in order to prevent stolen and counterfeit drugs that are being distributed as legitimate pharmaceutical products from entering the supply chain.

The risk of counterfeit and diverted medicines in the U.S. drug supply has not abated over the years. The Food and Drug Administration announced three times in the past year that it had discovered counterfeit Avastin – a critical drug used to treat several types of advanced cancer – in the United States. The FDA issued letters to clinical practices in California, Texas, and Illinois warning that they may have knowingly or unknowingly purchased and administered treatments missing active ingredients to cancer patients.

In 2012 in New York, 48 individuals were charged in a huge criminal diversion and fraud scheme to buy prescription drugs “on the street,” re-package or re-label them and sell them back into distribution through licensed pharmaceutical wholesalers, who in turn sold the drugs to pharmacies. These “recycled” medicines put patients at risk of contaminated or compromised drugs. In addition, authorities estimated the large-scale drug diversion scheme cost the New York state Medicaid program $500 billion. Similar schemes in other states are well documented, including one in Tennessee earlier this year that cost the state Medicaid program more than $58 million.

These incidents represent an unacceptable risk to patients. We urge the Energy and Commerce Subcommittee on Health to consider a strong unit-level serialization and traceability framework that appropriately secures and protects the distribution of medicines in the U.S. in a timely fashion.

Thank you for the opportunity to comment.

National Research Center for Women & Families

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